Christopher DeCoro
David N. Draper
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446–4800
christopher.decoro@kirkland.com
david.draper@kirkland.com

Attorneys for Plaintiff Microspherix LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MICROSPHERIX LLC, *Plaintiff*, v. MERCK SHARP & DOHME CORP., MERCK SHARP & DOHME B.V., AND ORGANON USA, INC., *Defendants.*	Civil Action No. 2:17-cv-03984-CCC-MF **JURY TRIAL DEMANDED** *Document Filed Electronically*

PLAINTIFF'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF EXHIBITS

Abbreviation	Description	Exhibit[1]
'037 Patent	U.S. Patent No. 8,722,037	Ex. 14 (as an enclosure)
'193 Patent	U.S. Patent No. 6,514,193	Ex. 22
'401 Patent	U.S. Patent No. 9,636,401	Ex. 2
'402 FH	Excerpts from the file history of U.S. Patent Application No. 14/711,658	Ex. 16, Ex. 31, Ex. 34
'402 FH Interference Req.	'402 File History, Request for an Interference, 5/13/2015	Ex. 14
'402 IPR FWD	IPR2018-00393, Final Written Decision, dated July 8, 2019	D.I. 104, Ex. 5
'402 IPR Petition	IPR2018-00393, Petition for *Inter Partes* Review, dated December 22, 2017	Ex. 20
'402 Patent	U.S. Patent No. 9,636,402	Ex. 3
'835 Patent	U.S. Patent No. 8,821,835	Ex. 1
Advanced Monte Carlo	B. Perot et al., "Spectrum Shape Analysis Applied to Radioactive Waste Gamma-Ray Spectroscopy," in Advanced Monte Carlo for Radiation Physics, Particle Transport Simulation and Applications (2001), pp. 413–18.	Ex. 15
Alonso	María J. Alonso et al., "Biodegradable Microspheres as Controlled-Release Tetanus Toxoid Delivery Systems," Vaccine 12(4): 299–306 (1994)	Ex. 29
Chattaraj	Sarat C. Chattaraj et al., "Biodegradable Microparticles of Influenza Viral Vaccine: Comparison of the Effects of Routes of Administration on the In Vivo Immune Response in Mice," J. Controlled Release 58:223–232 (1999)	Ex. 28
A61K 49/00	USPTO classification description for A61K 49/00	Ex. 32
A61L 31/16	USPTO classification description for A61L 31/16	Ex. 33
Fowler 2000	Jackson E. Fowler, Jr. et al., "Evaluation of an Implant That Delivers Leuprolide for 1 Year for the Palliative Treatment of Prostate Cancer," Urology	Ex. 27

[1] Exhibits 1–10 were attached to the Declaration of Tasha Gerasimow, filed with Microspherix's Opening Brief (D.I. 107). Exhibits 11–34 are attached to the Declaration of David N. Draper, filed concurrently herewith.

Abbreviation	Description	Exhibit[1]
	55:639–642 (2000)	
Invalidity Contentions	Merck's Second Amended Invalidity Contentions, dated August 17, 2020	Ex. 17
JCCS	Joint Claim Construction Statement, dated September 8, 2020	D.I. 94
Merck Op. Br.	Merck's Opening Claim Construction Statement, dated October 29, 2020	D.I. 103
Microspherix Op. Br.	Microspherix LLC's Opening Claim Construction Brief, dated October 29, 2020	D.I. 107
Mosby's	Mosby's Medical, Nursing, & Allied Health Dictionary, Sixth Edition (2002)	Ex. 21
Park 1998	Eun-Seok Park et al., "Biodegradable Polyanhydride Devices of Cefazolin Sodium, Bupivacaine, and Taxol for Local Drug Delivery: Preparation, and Kinetics and Mechanism of in Vitro Release," J. Controlled Release 52:179–189 (1998)	Ex. 24
Park Decl.	Declaration of Kinam Park, Ph.D. in Support of Defendants' Claim Construction, date October 29, 2020	D.I. 103, Ex. 1
Park Dep. Ex. 6, Hillery & Park	Drug Delivery: Fundamentals & Applications (Anya M. Hillery & Kinam Park, eds., 2nd ed. (2017))	Ex. 12
Park Tr.	12/10/2020 Deposition Transcript of Dr. Kinam Park	Ex. 11
Patents-in-Suit	'401 Patent, '402 Patent, and the '835 Patent	–
PDR (54th ed., 2000)	Physicians' Desk Reference, 54th Edition (2000)	Ex. 30
Product Monograph Implanon NXT™	Product Monograph of Implanon NXT™ (2012)	Ex. 23
Rosa 1994	G. De Rosa et al., "Influence of the Co-Encapsulation of Different Non-Iconic Surfactants on the Properties of PLGA Insulin-Loaded Microspheres," J. Controlled Release 69:283–295 (2000)	Ex. 26
Sanchez 1995	Alejandro Sánchez et al., "*In Vivo* Study of the Tissue Distribution and Immunosuppressive Response of Cyclosporin A-Loaded Polyester Micro- and Nanospheres," Drug Delivery 2:21–28 (1995)	Ex. 25

Abbreviation	Description	Exhibit[1]
U.S. Pat. App. 10/592,725, 7/20/2010 Applicant Resp.	7/20/2010 Amendment to Support Request for Continued Examination (RCE) Under the Provisions of 37 CFR § 1.114 and Supplemental Information Disclosure Statement, U.S. Patent Application No. 10/592,725, dated July 20, 2010	Ex. 18
U.S. Patent No. 10,413,504	U.S. Patent No. 10,413,504 to de Graaff et al.	Ex. 13
U.S. Patent Pub. 2019/0216725 A1	U.S. Patent Application Publication No. 2019/0216725 to Barnett et al.	Ex. 19

I. INTRODUCTION

Having failed to invalidate the Asserted Patents before the PTAB and Federal Circuit, Merck now seeks to escape infringement by using the *Markman* process to inject new limitations into the claims that have no basis in the claim language or intrinsic evidence. Merck flips the hierarchy of claim construction evidence on its head in relying first and foremost on extrinsic expert testimony and dictionary definitions rather than the patent's claim language and description of the invention. This backwards approach leads to Merck pursues constructions that would exclude from the claims express embodiments that are clearly contemplated in the specification of the Asserted Patents. And Merck's effort to effectively revise the claims with narrowing limitations because the term "brachytherapy" appears in the patents both misconstrues the teachings of the patents (which clearly teach a therapeutic approach with applicability beyond cancer tumor treatment) and misapplies the law (which instructs that claim construction construe the actual words used in the claims, and rejects importing general concepts from elsewhere).

Not only do Merck's arguments find little support in the intrinsic evidence or the law, they also bear little resemblance to the claim construction positions Merck took in its recent (and unsuccessful) IPRs contending that the Asserted Patents were invalid. To support this about-face Merck now provides an expert declaration—from a new expert, having jettisoned its expert from the IPRs—to provide "support" for its contrived constructions where the claim language and intrinsic evidence do not. As discussed below, the Court should reject Merck's strained, litigation-driven constructions and adopt Microspherix's proposed constructions, which are grounded in the intrinsic evidence and reflect the plain and ordinary meaning of the disputed terms.

II. DR. PARK'S DECLARATION SHOULD BE GIVEN NO WEIGHT

Lacking support in the intrinsic evidence for its radical claim construction proposals, Merck supplies the declaration of its new expert Dr. Kinam Park. But the Federal Circuit has

cautioned against over-reliance on expert testimony in the context of claim construction, and Dr. Park's declaration presents exactly the type of unsupported assertions at odds with the intrinsic record that should be afforded no weight.

This Court is well aware of the Federal Circuit precedent establishing the prominence of intrinsic evidence in guiding claim construction decisions, and that "extrinsic evidence . . . [i]s less reliable than the patent and its prosecution history in determining how to read claim terms." *Phillips v. AWH Corp*., 415 F.3d 1303, 1318 (Fed. Cir. 2005). This is especially so for "extrinsic evidence consisting of expert reports and testimony[, which] is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* While expert evidence can have some limited value in certain circumstances, "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. Similarly, a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id.* (internal quotation marks omitted). Viewed in the context required by this precedent, Dr. Park's declaration sheds no useful light on the meaning of the disputed terms.

First, as a threshold matter, Dr. Park's declaration should be disregarded because he did not analyze the meaning of the claims in the context of the intrinsic record. *Phillips*, 415 F.3d at 1313 (holding that one "cannot look at the ordinary meaning of the term . . . in a vacuum," and instead "must look at the ordinary meaning in the context of the written description and the prosecution history."). Despite the fundamental role of the written description and prosecution history in assessing claim meaning, Dr. Park admitted that he did not consider the totality of either

in forming his opinions as to a POSA's[2] understanding of the terms "therapeutic/prophylactic agent," "target tissue," and "polymeric coating."

For example, although Dr. Park noted that the specification cites "hundreds" of prior art publications, he conceded at his deposition that he had not reviewed all of them, and his report examined just ***two*** cherry-picked references in analyzing the terms "therapeutic agent" and "prophylactic agent." Park Tr. 19:6–14; 34:25–35:3; Park Decl. ¶¶ 42, 86. Dr. Park's limited review results in conclusions that are contradicted by the full intrinsic record. For example, with regard to the terms "therapeutic agent" and "prophylactic agent," Dr. Park broadly opined that "***[e]very one*** of the dozens of specific drugs and other agents listed in the patent, including by citation to prior art publications, are agents for the treatment or prevention of disease." Park Decl. ¶ 85 (citing ¶¶ 41–43).[3] But as explained further below (§ III.D), there are numerous references cited in the specification that describe drug classes that are ***not*** limited to the treatment or prevention of "disease" as Dr. Park so narrowly opined. Similarly, for the term "target tissue," Dr. Park broadly stated that "***every*** embodiment of the invention is directed to treating disease in tissues local to the site of implantation." Park Decl. ¶ 79. But again, as explained below (§ III.E), references cited in the specification (that Dr. Park failed to review) disclose therapeutic agents that act systemically rather than locally at the site of implantation. Dr. Park's selective head-in-the-sand approach results in flawed opinions that simply ignore the parts of the intrinsic record that are unhelpful to Merck.

Compounding the problem, Dr. Park also did not review the full prosecution history in

[2] Similar to Merck's proposed definition (Merck Op. Br. at 9), Microspherix contends that a person of ordinary skill in the art at the time of the inventions ("POSA") would have a Master's degree and several years of experience in the field of pharmaceutics, bioengineering, mechanical engineering, and/or materials science, or, alternatively, a Ph.D. degree in the same field, and may have also had experience working with or designing medical implants for use in the human body.
[3] Emphasis added throughout the brief, unless otherwise noted.

forming his opinions. Park Tr. at 143:11–22 ("***I did not read [the prosecution history] for the, you know, terms***. I just read the proposed claim terms and see whether that those are consistent with what POSA will think. . . . ***So, this particular information might — may not have been relevant to what I did in my report***."); 150:23–151:3; 154:1–10; 186:2–3 (trying to excuse his failure to review by contending a "POSA will not go to the file history"). Among other things, Dr. Park disregarded the interference request made by named inventor Dr. Kaplan during patent prosecution, which alleged that the pending claims of the '402 Patent overlapped with Merck's U.S. Patent No. 8,722,037 covering the accused product.[4] This evidence, which is indicative of Dr. Kaplan's understanding of such terms as "marker," "polymer coating," "therapeutic agent," "prophylactic agent," and "flexible," forms part of the intrinsic evidence and must be considered. *See Phillips Petroleum Co. v. Huntsman Polymers Corp.*, 157 F.3d 866, 872 (Fed. Cir. 1998). In ignoring the prosecution history, Dr. Park disregarded "evidence of how the PTO and inventor understood the patent" (*Phillips*, 415 F.3d at 1317), and in so doing presented opinions lacking the context of the full intrinsic record.

Dr. Park's failure to review much of the intrinsic record before offering his sweeping and unsupported opinions confirms that his opinions should be afforded no weight. *Phillips*, 415 F.3d at 1318; *see also Baxter Diagnostics Inc. v. PB Diagnostic Sys., Inc.*, 57 F.3d 1082 (Table), 1995 WL 253177, at *5 (Fed. Cir. 1995) (finding an expert's affidavit "flawed," "unsupported and conclusory," and not properly invoked by plaintiff in part because the expert did "not mention the . . . prosecution history, much less attempt to reconcile [it] with [his] litigation-induced claim interpretation"); *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1577–78 (Fed. Cir.

[4] Park Tr. at 142:7–13 ("Q. Do you know what an interference proceeding is? A. Actually, I'm not familiar with that."); D.I. 90 ¶ 246.

1995) (giving no weight to expert testimony that did not consider the prosecution history and provided only "conclusory legal opinions").

Second, Dr. Park's strained opinions also should be rejected because they even conflict with the parties' agreed-upon constructions. Dr. Park adopted a construction of "strand" that deviates from the parties' previously agreed-upon construction of "elongated implant." D.I. 94 (JCCS) at 2. Dr. Park inexplicably construed "strand" to be narrowly limited to "brachytherapy" treatment, which he then narrowly construed to be limited to cancer tumor treatment. Park Tr. at 73:3–9 ("Strand is described as a brachytherapy in this whole patent. The whole patent is about brachytherapy. ***A strand is obviously for brachytherapy***."); *see also id.* at 40:2–24, 72:3–4; 74:17–19; 79:17–19; 89:6–15; 90:16–21; 91:2–4; 125:1–3; 133:18–134:3. In basing his opinions on the mistaken assumption that the claimed "strand" "is obviously ***for*** brachytherapy" (*id.* at 73:3–9), Dr. Park improperly attempted to narrow the claims to only certain uses of these strands, which he then used as support to turn these broadly-applicable composition claims into narrowed method claims. *See Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 995 (Fed. Cir. 2000) (holding court correctly refused to narrow scope of composition claims to specific uses, since doing so would "mutate" them into method claims).

This misguided attempt to limit the asserted claims to Dr. Park's narrow view of "brachytherapy" taints all of his opinions. For example, based on this erroneous assumption, Dr. Park concluded that, "[i]n the context of the claimed invention, in which the ***brachytherapy*** implants are implanted into the tissue they target, the 'target tissue' is also the tissue into which implantation is intended." Park Decl. ¶ 77; Park Tr. 89:16–21 ("Strand[s] are used for brachytherapy. Whole patent is about brachytherapy. Specification is about brachytherapy. So claims, POSA would understand, they are claiming for brachytherapy, which is for localized

delivery."). Dr. Park's erroneous effort to read in his narrow view of "brachytherapy" is a necessary pre-condition to the narrow claim construction of "target tissue" that he offered, as reflected by the fact that a textbook he co-edited utilized the term "target tissue" to refer to the place of initial administration of the drug, even in the context of drug delivery for systemic treatment. Ex. 12 (Park Dep. Ex. 6, Hillery & Park) at 219 ("The 'target tissue' for most transdermal delivery approaches is the highly vascularized and immunologically rich dermal layer. In humans, the blood vessel . . . provid[es] sufficient access to the ***systemic*** circulation for rapid uptake."); Park Tr. 116:16–117:4, 121:20–124:5 (agreeing that in a textbook where he was named a co-editor, "'target tissue' means where blood vessel is dense, so that drug can be absorbed").

Because Dr. Park's opinions conflict with the parties' agreed-upon construction of "strand" and violate fundamental principles of claim construction, this is yet another reason his opinions should be given no weight. *See Depomed, Inc. v. Actavis Elizabeth LLC*, Civ. A. No. 12-1358 (JAP), 2014 WL 4215435, at *21 (D.N.J. Aug. 25, 2014) (giving expert testimony "little, if any, weight" because the expert "chose to ignore" the parties' agreed-upon claim construction).

Third, Dr. Park's declaration also consists of conclusory say-so, unsupported by any evidence, further warranting rejection. For example, with regard to the term "polymeric coating," Dr. Park opined that "'[c]oating,' and therefore 'polymeric coating,' has a customary meaning in the art and is defined by the process by which it is formed—*i.e.*, it is *coated* on the surface of an existing substrate." Park Decl. ¶ 89 (emphasis in original). But Dr. Park cited no authority or evidence for this conclusory statement. Based on this unsupported assertion, Dr. Park also opined that "polymer coatings" expressly ***exclude*** polymer "skins" that are formed simultaneously with the underlying surface. *Id.* at ¶ 91. When pressed at his deposition, Dr. Park admitted that Merck's construction conflicts with Dr. Kaplan's request for an interference proceeding, in which Dr.

Kaplan made clear that his claimed "polymer coating" specifically included such polymer "skin[s]." Park. Tr. at 183:4–184:6. Dr. Park's contradictory and unsupported conclusions should be afforded no weight. *See Phillips*, 415 F.3d at 1318 ("[C]onclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court.").

III. PROPOSED CONSTRUCTIONS

A. "marker"[5]

Merck's bizarre effort to construe the common concept of a "marker" to require a marker of particular toxicity, and in particular "a substance less toxic than barium sulfate," is factually and legally unsupported and must be rejected.

1. Merck Mischaracterizes the IPRs and Misapplies Relevant Law

The Court should reject Merck's proposed construction that limits "marker" to exclude barium sulfate and substances that are more toxic than barium sulfate. Merck bases its construction on gross misrepresentations of the IPR record and the law.

Merck seemingly admits that its position depends on establishing either prosecution history disclaimer or judicial estoppel. Neither are applicable. As to prosecution history disclaimer, Merck "bears the burden of proving the existence of a 'clear and unmistakable' disclaimer that would have been evident to one skilled in the art." *Mass. Inst. of Tech. v. Shire Pharm., Inc.*, 839 F.3d 1111, 1119 (Fed. Cir. 2016). This is a "high" and "demanding" standard. *See Galderma Labs., L.P. v. Sun Pharm. Indus. Ltd.*, C.A. No. 16-1003-LPS, 2017 WL 5592278, at *3–4 (D. Del. Nov. 21, 2017). Similarly, in order for judicial estoppel to apply, "the party who is to be estopped must have succeeded in maintaining a contrary legal position in a prior proceeding." *See Smart Vent Prods., Inc. v. Crawl Space Door Sys., Inc.*, Civ. A. No. 13-5691 (JBS/KMW), 2019 WL 1116238, at *3

[5] The parties' proposals for all terms are summarized in the Table of Proposed Constructions.

(D.N.J. Mar. 11, 2019) (internal citation omitted). Merck is unable to meet either of these strict standards as the record, including Microspherix's arguments and the PTAB's decision in the IPRs, supports that barium sulfate is certainly ***within*** the scope of "marker."

Microspherix did ***not***, as Merck would lead this Court to believe, disclaim "barium sulfate" from the scope of "marker" during the IPR proceedings. Nothing of the sort. Rather, the record shows that Microspherix and the PTAB specifically acknowledged that barium sulfate was ***within*** the scope of the claims. In the IPRs, Merck asserted the claims were obvious because a POSA "would have retained the polymer of De Nijs and added the barium sulfate marker of Schopflin to arrive at the claimed implants." D.I. 104, Ex. 5 ('402 IPR FWD) at 24–25. *Id*. With respect to dependent claims reciting implants with "open ends," Microspherix argued in response, and the PTAB agreed, that there was no motivation to combine these references, or a reasonable expectation of success in doing so, because a POSA "would not have added barium sulfate to a device ***with open ends*** because of potential toxicity from leaching barium." D.I. 104, Ex. 5 ('402 IPR FWD) at 28–30 ("Patent Owner also argues that a [POSA] 'would have concerns about potential adverse effects of leakage [of barium sulfate] out of the ***unsealed ends*** in an undesired amount.'"); *see also* D.I. 104, Ex. 30 ('401 IPR FWD) at ("Patent Owner argues that a [POSA] would not have been motivated to add, or expected success, in adding a marker component (like barium sulfate) to an open-implant's core").

The fact that the PTAB found there was no motivation to combine the barium sulfate marker from Schopflin with De Nijs' device confirms that barium sulfate is ***within*** the scope of the claims. If the claims did not cover barium sulfate, the PTAB would have had no reason to consider a POSA's knowledge of barium sulfate in assessing motivation to combine and

reasonable expectation of success.[6]

The fact that toxicity concerns might have de-motivated a POSA from pursuing a combination of an open-ended device with a barium sulfate marker does not somehow transform the claim term "marker" in these patents into something with a particular toxicity requirement. Indeed, Merck fails to mention that the PTAB specifically found that barium sulfate met the marker limitation of independent claim 1 of the '402 Patent ("a radio-opaque material") in finding that claim invalid. D.I. 104, Ex. 5 ('402 IPR FWD) at 22–24. Thus, the facts clearly demonstrate there was no disclaimer. The reason this claim was invalidated while others were upheld is because a POSA would not have been motivated to include Schopflin's barium sulfate marker into implants having "openings" or "open ends" (like the remaining Asserted Claims), ***not*** because of any claim construction of "marker" that would exclude barium sulfate or other markers more toxic than barium sulfate.

Tellingly, Merck cites no legal precedent suggesting that the types of argument Microspherix made during the IPRs relating to motivation to combine and expectation of success amount to a "clear and unmistakable" disclaimer (*Mass. Inst. of Tech.*, 839 F.3d at 1119), or that such arguments could establish an admittedly "silent" limitation. Merck Op. Br. at 38. The cases Merck does cite, *Southwall* and *Aylus*, are inapposite. *See id.* at 37. In *Southwall*, the patentee disclaimed a "sputter-deposited dielectric" encompassing a two-step process by expressly arguing during prosecution that the amended claim was directed to a one-step process. *See Southwall*, 54 F.3d at 1576–77. In *Aylus*, the patentee's repeated statements in an IPR regarding the meaning of

[6] Indeed, Merck agrees that reasonable expectation of success "applies only to claim elements." Merck Op. Br. at 35. Notably, although the Board found no reasonable expectation of success based on a POSA's knowledge of "leaching of the material from devices," Merck does not seek to include this negative limitation within its claim construction. D.I. 104, Ex. 5 ('402 IPR FWD) at 32.

the claims to distinguish prior art references "constitute[d] a clear and unmistakable surrender of [certain] methods," where those statements led the Board to find the petitioner failed to show that "the asserted prior art ***met the limitations***" being construed. 856 F.3d at 1363. Here, Microspherix never argued that Schopflin's barium sulfate did not meet the "marker" limitation; to the contrary, Microspherix readily agreed that Schopflin's barium sulfate was a marker. There is thus no basis to insert any such negative limitation to narrow the claim scope. *See, e.g.*, *BASF Corp. v. SNF Holding Co*. No. 4:14-CV-2733, D.I. 122, at 17–20 (S.D. Tex. Jan. 6, 2017) (rejecting similar attempt to limit the claims based on a patentee's arguments regarding the prior art and a lack of reasonable expectation of success).

For the same reasons disclaimer is inapplicable, judicial estoppel does not apply. Merck Op. Br. at 38. Microspherix never argued that "barium sulfate" was outside the scope of the claims during the IPRs. Thus, Microspherix does not advance any "contrary legal positions" required for judicial estoppel and this doctrine cannot apply. *Smart Vent Prods.*, 2019 WL 1116238, at *3.

2. Intrinsic Evidence Makes Clear "Marker" Includes Barium Sulfate

Aside from the IPR record, the claims, the specification and the prosecution history each provide further confirmation that barium sulfate is within the scope of the term "marker."

The specification states "[m]arkers are typically made of high atomic number (i.e., 'high Z') elements or alloys or mixtures containing such elements," listing examples including silver. '402 Patent at 2:29–34 and 10:37–44. During the IPRs, Merck and its expert Dr. Langer pointed to these same passages in the specification to argue that the "'402 patent uses the term 'high Z' as a synonym for high atomic number elements such as silver," and that "barium in barium sulfate has a higher atomic number than silver and is therefore a high Z material." D.I. 104, Ex. 5 ('402 IPR FWD) at 33. With respect to claim 3 of the '402 Patent, which recites a "radio-opaque material compris[ing] a high Z element," the Board credited Dr. Langer's testimony to "find that barium is

a high Z element and that barium sulfate is a high Z material." *Id*.[7] Merck's proposed construction flies in the face of the same disclosures of the specification that it successfully relied upon in the IPRs.

In sum, the intrinsic record confirms that barium sulfate is within the scope of the "marker" term, and Merck failed to identify anything that would constitute a ***clear and unmistakable*** disclaimer otherwise. The Court should reject Merck's meritless attempt to exclude barium sulfate from the claims.

B. "marker component"

"Marker component" is a simple concept—a component that contains a marker—that Merck attempts to distort in order to narrow and introduce ambiguity. The Court should reject Merck's construction of "marker component" because it improperly attempts to read in a limitation that the "marker" ***is*** "***part*** of the seed or strand," and in doing so improperly narrows the claims to the exclusion of embodiments disclosed in the specification. Merck Op. Br. at 23.

Merck cites ***nothing*** in the intrinsic record to support any construction that deviates from the plain meaning. Instead, consistent with the intrinsic evidence, the term "marker component" should be afforded its plain and ordinary meaning as understood by a POSA: "a component of a

[7] Dr. Kaplan's request for an interference also confirmed that the scope of his pending '402 Patent claims encompassed barium sulfate radio-opaque material. Specifically, Dr. Kaplan stated that pending claim 29 reciting "the radio-opaque material comprises a high-Z element" was "not patentably distinct from" claim 4 of Merck's '037 Patent, reciting "wherein the radio-opaque material is barium sulphate"—"a species ***which falls within the scope of claim 29***." Ex. 14 ('402 FH Interference Req., 5/13/2015) at 4–5, 8–9. Dr. Kaplan stated that "it was common knowledge that barium sulfate includes a high Z element." *Id*. at 8 (citing "Advanced Monte Caro [sic] For Radiation Physics, pp 413-418 (2001)"); Ex. 15 (*Advanced Monte Carlo*) at Abstract ("high-Z elements, such as barium (Z=76)"). A POSA reading the prosecution history would therefore conclude that the scope of the "marker" terms ***include*** barium sulfate. *See Mass. Inst. of Tech.*, 839 F.3d at 1120 (rejecting arguments that patentee disclaimed a type of tissue from term "vascularized organ tissue," as patentee's conduct "during prosecution . . . reinforces our conclusion that the asserted claims as issued include [that tissue type] within their scope").

device that comprises a marker." This definition is consistent with embodiments shown in Figs. 3A–3F of the '402 Patent, where the "radiopaque marker 30 is ***attached*** to strand 10 via the biocompatible component 12 and/or the therapeutically active component 14." '402 Patent at 18:26–52. The words "attached to" confirm that the marker component is not necessarily "part of" the seed or strand as Merck contends. Merck's effort to encourage a construction of "marker component" that excludes express embodiments, and ultimately leads to a potentially nonsensical reading of the claim, must be rejected. *See Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276–77 (Fed. Cir. 2008) (collecting cases for the proposition that the Federal Circuit "normally do[es] not interpret claim terms in a way that excludes embodiments disclosed in the specification").

C. "radiopaque" and related terms[8]

Merck argues that its construction of "radiopaque" should be adopted because it "is taken word-for-word from the specification." Merck Op. Br. at 40. But the same can be said for Microspherix's construction. '402 Patent at 18:61–62 ("strand can be ***visualized*** by X-ray"). Unlike Merck's construction, Microspherix's construction also finds further support throughout the prosecution history. During prosecution of the '402 Patent, Dr. Kaplan responded to the Examiner's rejection over the prior art by pointing out that the claimed "strand provides for control of placement (via ***visualization***)," and that "removal of the [claimed] strand is possible when the particular agent is no longer needed/desired, because one can ***locate*** the strand by virtue of the presence of a radiopaque material that ***allows for the position of the strand to be determined*** following administration" Ex. 16 (402 FH, Nov. 8, 2016 Response) at 5.

Microspherix thus presents the most correct and precise construction based on intrinsic

[8] Insofar as Merck's proposed constructions for these terms also inject the "less toxic than barium sulfate" additional limitation, they are further unsupported by the intrinsic evidence and Federal Circuit case law as discussed in detail above in § III.A.

evidence, with a level of precision that was unnecessary for purposes of the IPR proceedings (where the parties did not contest whether the relied-upon references contained radiopaque markers). D.I. 104, Ex. 5 ('402 IPR FWD) at 33. Moreover, Microspherix's construction is in fact consistent with previous statements made by Merck. For example, in Merck's invalidity contentions, Merck argued that the "radio-opaque" claim elements allegedly were met by prior art products that included "barium sulfate, within the core of the device, to allow for the ***visualization*** and imaging of the device using x-ray following implantation." Ex. 17 (Invalidity Contentions), Exhibit 01 at 6-7, 10-11. As another example, during the prosecution of its '037 Patent, Merck acknowledged that radiopaque material helps "***visualize*** the implant with X-ray techniques." *See* Ex. 18 (U.S. Pat. App. 10/592,725, 7/20/2010 Applicant Resp.) at 12. And more recently in another patent application, Merck defined a "radiopaque" component as one that "will cause the implant to be X-ray ***visible***." Ex. 19 (U.S. Patent Pub. 2019/0216725 A1) at [0025].

D. "therapeutic agent"; "prophylactic agent"

Turning a blind eye to the express teachings in the intrinsic record that these terms encompass agents that exert a medically beneficial or physiological effect, Merck asks the Court to limit "therapeutic agent" and "prophylactic agent" to only those agents that specifically treat or prevent "disease," a thinly-veiled attempt to exclude contraceptives from the scope of the claims.[9] Not only is Merck's position contrary to the intrinsic record, it also flies in the face of the positions that Merck and its now-jettisoned IPR expert took in arguing (without any disagreement from Microspherix) that prior art contraceptive implants ***did*** in fact contain therapeutic and/or prophylactic agents. Ex. 20 ('402 IPR Petition) at 50–51 ("De Nijs and Schopflin both teach

[9] Although Merck's construction is plainly wrong in light of the intrinsic evidence, Merck is further wrong that POSAs would not technically consider pregnancy to be a "disease." Merck Op. Br. at 22. At the very least, this would be a factual issue for a jury to ultimately decide.

implantable polymer devices that release contraceptive hormones as therapeutic agents," citing Declaration of Dr. Langer), 53–54 (same); D.I. 104, Ex. 5 ('402 FWD) at 11. Merck's position is simply not credible.

Merck improperly starts with extrinsic evidence in contending its proposed constructions are the "commonly accepted definitions" known to a POSA, referencing Dr. Park's declaration and various extrinsic dictionaries. Merck Op. Br. at 21. As described above, however, Dr. Park's opinions based on these extrinsic references should be afforded no weight at least because he failed to review the relevant ***intrinsic*** evidence, including the references cited in the specification and the file history. *See supra* § II. In any event, the extrinsic dictionaries cited by Merck actually support Microspherix's constructions because they confirm that the terms "therapeutic agent" and "prophylactic agent" are not limited to specifically treating or preventing "diseases." For example, although Merck relied on Mosby's dictionary definition for "prophylactic," Merck omitted the pages containing a definition for "therapeutic," which makes no mention of "disease" and instead defines "therapeutic" broadly as "beneficial" and "pertaining to a treatment." Ex. 21 (Mosby's) at 1699. Similarly, other dictionaries Merck relies upon define prophylactic broadly as "tending to prevent or ward off" generally, and also "contraception" specifically, contrary to the end-goal of Merck's gambit. Merck Op Br. at 22; D.I. 104, Ex. 9 (Merriam-Webster's) at 670 (definitions of "prophylactic," including "tending to prevent or ward off," "something (as a medicinal preparation) that is prophylactic," "a device and esp. a condom for preventing . . . conception"); Ex. 1 (Tabers) at 1763 ("prophylactic" includes "a condom"); Ex. 10 (Mosby's) at 1413 ("prophylactic" includes "a condom").

Merck's effort to then rely on select portions of the intrinsic record also fails in the face of the rest of this record that confirms Microspherix's position. *First*, Merck's implication that the

various headings in the specification restrict the meaning of "therapeutic agent" and "prophylactic agent" to the treatment or prevention of "disease" is unsupported by law and the facts. Merck Op. Br. at 21. None provides an explicit disclaimer, and Merck cites no case in which headers or descriptions alone rose to level of explicit disclaimer. *Id*. In fact, courts have routinely held otherwise. *See Pitney Bowes, Inc. v. Hewlett–Packard Co.*, 182 F.3d 1298, 1312 (Fed. Cir. 1999) ("[I]f we do not read limitations into the claims from the specification that are not found in the claims themselves, then we certainly will not read limitations into the claims from the patent title."); *Moore U.S.A., Inc. v. Standard Register Co*., 229 F.3d 1091, 1111 (Fed. Cir. 2000) (declining to limit construction to preferred embodiment in the title).

Second, the fact that the specification discusses brachytherapy does not limit the claims to brachytherapy or the historical cancer tumor treatment first associated with this technology. *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) ("We do not read limitations from the specification into claims; we do not redefine words. Only the patentee can do that."); *Liebel–Flarsheim Co. v. Medrad, Inc*., 358 F.3d 898, 906 (Fed. Cir. 2004) (requiring "explicit disclaimer"). Indeed, had Dr. Kaplan "intended to limit the disputed claim terms to [brachytherapy], [he] could have easily done so by explicitly modifying the disputed claim language with [that] term." *SuperGuide Corp. v. DirecTV Enters., Inc*., 358 F.3d 870, 880 (Fed. Cir. 2004). In fact, Dr. Kaplan did just that in reciting "brachytherapy seed" in the claims of the non-asserted U.S. Patent No. 6,514,193. Ex. 22 ('193 Patent) at Claims 1, 5; *see Enzo Biochem, Inc. v. Applera Corp*., 599 F.3d 1325, 1333 (Fed. Cir. 2010) (finding no basis to "read a 'hybridization' requirement" into the claims, as the patentee "knew how to claim a linkage group [with that requirement], as they did in [related] patents, but specifically omitted that language from the claims of the [patent at issue]"). The claims of the Asserted Patents contain no such limitation.

Failing to find explicit disclaimer required to narrow the terms to treatment or prevention of "disease," Merck advances its argument based on alleged silence in the specification with respect to drugs used other than for the treatment or prevention of disease, including contraceptives. Merck Op. Br. at 22. While silence is not a sound basis to limit claims (*Oatey*, 514 F.3d at 1276−77), the patents are not in fact silent. The specification expressly describes the "therapeutically active component[s]" as something that "exert[s] an effect on the animal's physiology." '402 Patent at 16:36–41. And it then lists examples of drugs and classes used to affect a body's physiology, including many that are not designed specifically to treat a particular disease or disease state. '402 Patent at cols. 8–9.

Perhaps most directly contradicting Merck's effort to improperly narrow the scope of "therapeutic agent" is the fact that the specification and patent claims reference "hormones" as one of many "therapeutically active substances that can be combined with a biocompatible component." '402 Patent at 8:54-55 and 9:19–20; *id*. at claims 13 and 17. Merck has acknowledged that certain hormones, including contraceptives, are "therapeutic agents" in the context of this patent. For example, during the IPRs, Merck stated that "many types of drug-eluting implants were known and used outside of cancer treatment to deliver a wide array of ***therapeutic agents***, including ***hormones for birth control***, antibiotics, and various other compounds." Ex. 20 ('402 IPR Petition) at 9. Notably, in one of Merck's implantable drug delivery device patents (which shares a common inventor with Merck's '037 Patent), Merck describes hormones, and specifically contraceptive hormones, as "therapeutic agents." Ex. 13 (U.S. Patent No. 10,413,504) at 1:15–16 ("The present invention relates to the field of female contraception."); 9:55–66 ("first therapeutic agent is a progestogenic steroid compound . . . second therapeutic agent is an estrogenic steroidal compound"); *id*. at cover (listing inventor "Wouter De Graaff"); Ex. 14 ('402 FH Interference Req.,

5/13/2015) at encl., cover ('037 Patent listing same). Similarly, Merck's training materials for its hormone-containing Implanon NXT list "[c]ontraception" under the "***[t]herapeutic*** indication" section. Ex. 23 (Product Monograph Implanon NXT™) at 3.

As another example, the specification discloses bupivacaine as a "therapeutic agent," referencing an article describing implantable bupivacaine as an anesthetic for surgical pain. '402 Patent at 8:20–21 ("bupivicaine (Park…1998)"); Ex. 24 (Park 1998) at 180. This expressly disclosed "therapeutic agent" treats the ***condition*** or ***sensation*** of pain rather than any "disease."

The specification also teaches the use of "immunosuppressants," citing Sanchez, an article describing implantation of immunosuppressant cyclosporine following tissue transplants, in order to avoid rejection of the transplant by the immune system. '402 Patent at 9:21–22; Ex. 25 (Sanchez 1995) at 27. Cyclosporine is thus another disclosed "therapeutic" or "prophylactic agent" that has a medically-desirable effect on a patient's physiology (the immune system), as opposed to treating a "disease."

Dr. Kaplan's request for an interference also confirmed that the claimed "therapeutic agents" encompass hormones, ***including contraceptives***. Specifically, Dr. Kaplan compared his claim 27 reciting a "therapeutic agent," with claim 1 of the Merck patent reciting "a contraceptive":

Claims 27–35 of the present application	**Claims 1–5, 8, 11, 12, 16 and 19 of the '037 patent**
29. A device/strand for administration of a <u>therapeutic agent</u> to a subject in need thereof comprising (a) a therapeutically effective amount of a therapeutic agent; (b) a biocompatible component	1. A drug delivery device for subdermal administration of <u>a contraceptive</u> or hormone replacement therapy comprising (i) a core comprising (a) crystalline <u>desogestrel or 3-ketodesogestrel</u>; (b) a …

See Ex. 14 ('402 FH, Interference Req., 5/13/2015) at 4 (underlining emphases added). Dr. Kaplan told the Examiner that claims reciting a "therapeutic agent" specifically encompassed a "contraceptive" or "hormone" of the '037 Patent. *Id.* at 4.

The intrinsic evidence, showing hormones, anesthetics, and immunosuppressants (among dozens of other examples) are considered "therapeutic" or "prophylactic agents," demonstrates Merck is simply wrong in arguing "[***e***]***very*** exemplary drug in the patents is for the treatment or prevention of disease." Merck Op. Br. at 22 (citing Park ¶¶ 41–42, 85). As discussed above (§ II), Dr. Park admitted to an incomplete analysis ignoring art in the specification and key portions of the file history (Park Tr. at 142–143); his opinions, relying on cherry-picked extrinsic evidence, are therefore entitled to no weight. *Southwall*, 54 F.3d at 1578. Merck's constructions, which are rooted in a selective reading of the specification and improperly seek to the narrow the claims to read out disclosed embodiments, must be rejected.

E. "target tissue" and related terms

The parties agree that the claimed seeds/strands are implanted in the "target tissue." In fact, the parties' definitions track up to the point at which Merck asks the Court to import an additional limitation that the therapeutic effect of whatever is released from the device also takes place at the implantation site. Merck's effort to read in this additional limitation both ignores the structure of the claim (apparatus and not method of treatment, *see* Microspherix Op. Brief at 15), as well as the overwhelming intrinsic evidence that contradicts Merck's position.

Merck tries to justify its narrowing limitation based on the "brachytherapy context" of the specification and the fact that "[t]he intrinsic record never suggests that the implant may be located remotely to the tissue on which the agent is intended to act." Merck Op. Br. at 14. Merck is wrong both legally and factually. "Absent a clear disavowal or contrary definition in the specification or the prosecution history, [Dr. Kaplan] is entitled to the full scope of its claim language." *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004). No clear disclaimer or disavowal is present in the intrinsic record, and Merck does not even attempt to point to one.

In any event, the specification rejects any notion that the invention is limited to drug agents

that only act at the implantation site, as the patents list numerous therapeutic drugs that are delivered and act beyond the site of implantation. Merck self-servingly argues that the scores of possible drug candidates referenced in the patent are just a "listing of prior-art publications," and somehow not embodiments of the invention. Merck Op. Br. at 13, n. 7; Park Tr. at 160:4–16. But a simple review of the specification refutes Merck's position. The listing of drugs that can be used with the disclosed seeds and strands appears in the "Therapeutic and Diagnostic Agents" subsection of the "DETAILED DESCRIPTION OF THE INVENTION" section of the specification. '402 Patent at 7:65–9:30. The first paragraph of that section expressly states that "[a]ny of a wide range of therapeutic, diagnostic and prophylactic materials can be incorporated into the strands, including organic compounds, inorganic compounds, . . . using standard techniques." '402 Patent at 7:65–8:3. The next paragraph describes 24 different "non-radioactive" drug classes, which Dr. Park agreed could be used with the claimed invention, including antibodies, anti-viral agents, and hormones. '402 Patent at 8:4–15; Park Tr. 83:11–85:8. Indeed, during prosecution, Dr. Kaplan relied on this same disclosure when adding new a claim specifically reciting wherein "the therapeutic agent is a hormone." Ex. 16 ('402 FH at Nov. 8, 2016 Resp.) at 4 (citing Specification of Original App. at 13:11 and 13:13–14), ("at least at page 13, line 11, and lines 13–14,"); Ex. 31 ('402 FH, Original App.) at 13:11 (reciting "hormones").

The next paragraph of the specification, spanning more than 80 lines—which Merck claims is irrelevant to the invention—lists over 50 specific examples of therapeutic agents, including hormones, vaccines, and antibodies, that "***can be*** combined with a biocompatible component." '402 Patent at cols. 7–9; 8:16–18, and 8:51–55. In other words, rather than merely listing prior-art publications, the inventor describes these drugs as examples of the "wide range of therapeutic, diagnostic and prophylactic materials [that] can be incorporated into the strands, including organic

compounds [and] inorganic compounds." *Id*. at 7:65–8:1.[10]

Certain dependent claims in fact specifically recite "hormone[s]" as a "therapeutic agent." '402 Patent at claims 13 and 17. And the specification contains many examples of specific therapeutic agents that act systemically. In the hormone context, the specification expressly cites the Rosa 1994 article, which reports using polymeric microspheres of insulin to treat diabetes—a disorder that is treated systemically by raising glucose levels in the plasma (*i.e.*, blood), rather than in any local tissue. '402 Patent at 9:19–20; Ex. 26 (Rosa 1994) at 284; Park Tr. 32:22–33:23 (systemically acting drugs are "intended to go to the blood stream and then distributed throughout the body"), 68:23–69:11, 103:5–7 (agreeing insulin affects physiology), 169:25–170:6. The specification also identifies leuprolide for the treatment of prostate cancer, which is implanted in the arms to decrease levels of testosterone circulating throughout the body, and thus not limited to localized treatment. '402 Patent at 5 (citing "Fowler… (2000)") and 16:55 ("leuprolide"); Ex. 27 (Fowler 2000) at 640; Park Tr. 171:21–173:16.

The specification also references "vaccines," citing the Chattaraj paper, which describes the insertion of influenza viral vaccine in polymer microparticles below the skin (*i.e.*, subcutaneously), to "stimulate production of the ***systemic*** immune response." '402 Patent at 8:53–54; Ex. 28 (Chattaraj) at Abstract, 224–226; Park Tr. 93:15–20. The vaccine's insertion site was not the only site of intended therapeutic action—rather, ***systemic*** levels of vaccine and antigen were monitored after injection. *Id*. The specification also refers to "tetanus toxoids" vaccines,

[10] The patent classifications are not limited to "radioactive therapy and/or 'brachytherapy'" as Merck suggests. Merck Op. Br. at 17. For example, the '402 Patent lists on its face A61L 31/16 ("Biologically active materials, e.g. therapeutic substances") and A61K 49/00 ("Preparations for testing in vivo"), and the latter was also used in a search by the Examiner. '402 Patent at 1 (listing A61K 49/00 and A61L 31/16); Ex. 32 (description for A61K 49/00); Ex. 33 (description for A61L 31/16); Ex. 34 ('402 FH) at "Search Notes" (listing "A61K 49/00").

citing the Alonso paper, which describes their use to "induce[] a prolonged immune response against tetanus," and even prevent "***neonatal*** tetanus by maternal immunization." '402 Patent at 8:48; Ex. 29 (Alonso) at 300, 305. Such vaccines thus have therapeutic targets far beyond the local sites of injection.

The specification also discloses "antibodies," which are known to act systemically. '402 Patent at 7:60, 8:10, and 8:60; *id*. at 16:41–43 (citing Physician's Desk Reference to show "[m]yriad different substances can be used as the therapeutically active component"); Ex. 30 (PDR (54th ed., 2000), at 927–929 (entry for Remicade (infliximab), an "antibody" given by "intravenous infusion" (*i.e.*, into a patient's veins) to treat Crohn's disease, acting systemically to reduce "infiltration of inflammatory cells")). Dr. Park conceded as much when he could not identify a single antibody that acted locally at the site of implantation. Park Tr. at 85:13–25.[11]

Thus, the Asserted Patents encompass applications where the "target tissue" is not limited to the tissue on which the therapeutic agent produces its intended effect. Merck's construction improperly excludes these embodiments and must be rejected. *See Oatey*, 514 F.3d at 1276–77.

Thus, the specification and file history make clear the "target tissue" is the tissue in which

[11] Because the specification describes such therapeutic applications, the cases Merck relies on to argue that "Dr. Kaplan intended to limit all embodiments of his invention" (Merck Op. Br. at 17−18) are distinguishable, as in each, the Court found that the specification did not describe embodiments without the limiting feature, or expressly stated the limiting feature was required. *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004) (finding claims limited to certain feature because invention was "defined globally" in specification as requiring it); *Wireless Protocol Innovations, Inc. v. TCT Mobile, Inc.*, 771 F. App'x 1012, 1018 (Fed. Cir. 2019) (specification "clearly and repeatedly" stated that claimed method could not operate without limiting feature); *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1318 (Fed. Cir. 2014) (party opposing limiting construction had "not identified even a single embodiment" without the limiting feature); *SciMed Life Sys. v. Adv. Cardiovascular Sys.*, 242 F.3d 1337, 1344 (Fed. Cir. 2001) (finding claims limited, where specification expressly stated that "all embodiments of the present invention" had the limiting feature, which the Court found a "broad and unequivocal" disclaimer).

the implant is implanted, and not limited to where the therapeutic agent is intended to act.[12]

F. "polymeric coating"

The flaw in Merck's proposed construction of "polymeric coating" is readily apparent from its 27-word construction of this straightforward two-word phrase. Such complexity is not required to understand the plain and ordinary meaning of the term "polymeric coating" as "a layer of polymer." Merck's construction, which seeks to impose a specific process by which the polymer is applied, fails because Merck cannot prove that the proposed process step is "an essential part" of the claimed invention, to warrant the exclusion of other embodiments disclosed in the specification. *See Cont'l Circuits LLC v. Intel Corp.*, 915 F.3d 788, 799 (Fed. Cir. 2019) ("a product claim" is only limited to the process by which it is made if the patentee "has ***made clear*** that the process steps are an ***essential part*** of the claimed invention."); *see also Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372–73 (Fed. Cir. 2000) ("A novel product that meets the criteria of patentability is not limited to the process by which it was made.").

The intrinsic evidence is inconsistent with Merck's effort to read process limitations into this straightforward description of the claimed device. The specification states that "standard techniques" can be used "to form, or to coat" strands and seeds. '402 Patent at 7:63–8:3. For example, the specification discloses polymeric coatings and polymeric dispersions made by a "Phase Inversion" process, in which polymers are "dissolved," and then "mixed" with other components, rather than "appl[ied]" to "an existing surface." *Id*. at 12:32–46. The specification

[12] Merck's redundancy argument (Merck Op. Br. at 9–10) is also wrong. *First*, Merck overlooks that its proposed definition suffers from the same groundless critique, as it includes the same language as Microspherix. *See* '401 Patent at claims 1, 6, and 19. *Second*, there is no redundancy because it is not always the case that implants are positioned in the tissue in which they are in fact implanted—they can migrate—and that is the very issue that Dr. Kaplan's invention sought to solve. '402 Patent at 21:16–20 ("FIGS. 8A, 8B and 9 depict the addition of polymeric anchoring structures to brachytherapy strands. … As noted above, migration can be problematic.").

then describes another eight methods of preparing polymeric coatings and polymeric dispersions. *See id.* 11:21–14:19. Merck points to no statements by Microspherix that ***any*** process for "polymeric coating" is an "essential part" of the claimed invention, let alone the specific process that Merck proposes should limit the claimed invention. Merck Op. Br. at 28.

Lacking support in the intrinsic record, Merck turns to irrelevant extrinsic evidence and meritless critiques of Microspherix's proposed plain and ordinary construction—critiques equally applicable to Merck's construction. For example, Merck relies on Dr. Park's conclusory opinions, but as discussed above Dr. Park failed to consider Dr. Kaplan's interference request in which he confirmed the scope of "polymeric coating." *See supra* at § II; Merck Op. Br. at 28 (citing Park Decl. ¶¶ 88–89). Specifically, Dr. Kaplan compared his claims to the claims of Merck's '037 Patent, and told the Examiner that his claims reciting "polymeric coating" ***covered*** such "polymer skins." Ex. 14 ('402 FH, Interference Req., 5/13/2015) at 5. This expressly contradicts Merck's litigation-inspired argument that "polymeric coating" excludes polymer "skins" formed simultaneously with an underlying surface. Merck Op. Br. at 30–31.

Merck is also wrong that Microspherix's validity contentions justify its construction. Merck Op. Br. at 29. For one thing, any such contentions are at best forms of extraneous extrinsic evidence that have no place in the claim construction analysis. In any event, Microspherix's contentions distinguishing the claimed "polymeric coating" from the specific "sheath" and/or "hull" of certain alleged prior art, and Microspherix's '310 Patent claims allegedly "distinguish[ing] between a 'coating' and a 'sleeve,'"[13] speak nothing to whether the process for forming the "polymeric coating" is an "essential part" of the claimed invention. Merck Op. Br. at 29–30.

[13] Neither "coating" nor "sleeve" in those claims require any specific process of manufacture. Merck Op. Br., Ex. 14 ('310 Patent) at claims 39–42.

Finally, Merck incorrectly argues that Microspherix's construction reads out the meaning of "coating" entirely. Merck Op. Br. at 30. Microspherix's proposed construction instead gives the term "coating" in "polymeric coating" its plain and ordinary meaning: "a layer." Merck's effort to read in a narrow process requirement for applying the "polymeric coating" must be rejected, and the remainder of Merck's arguments regarding whether its product has a polymeric coating are (at best for Merck) factual issues of infringement and not issues of claim construction.

The Court should adopt Microspherix's plain and ordinary meaning of "a layer of polymer," and reject Merck's attempt to improperly read in a process limitation.

G. "hollow interior" and related terms

Merck's construction of "hollow interior" is wrong because it reads not one but ***two*** additional limitations into the claims: (1) that the hollow interior is "defined by and inside" the wall of the marker component, and (2) the continuing presence of an "empty" space. This construction is unsupported by the plain and ordinary meaning of the term and intrinsic evidence and Merck points to no evidence of clear disavowal or disclaimer to support these narrowing limitations.

First, Merck's definition improperly requires the hollow interior be "***defined by and inside***" the wall of the marker component. The claims and specification do not require as much from the term "hollow interior." While certain claims recite a "marker component" including a "substantially continuous wall," which is "bounding a hollow interior" ('401 Patent at claims 1, 20), that "wall" could have a hollow interior ***on either side*** of it. Based on the claim language, the "marker component" wall must only ***bound*** a "hollow interior," wherein agents and other components are disposed. And the "hollow interior" need only be "interior" to the strand as a whole, rather than specifically "interior" to the "marker component." In other words, nothing requires the "hollow interior" to be "defined by and inside" any portion of the marker component's wall.

The specification confirms that the potential configurations of the claimed components are not limited to the sole configuration Merck's construction would allow for. The specification states "radiopaque marker 30 is attached to strand 10 via the biocompatible component 12 and/or the therapeutically active component 14," and that "***[t]he exact manner***" that the marker is attached to the strand "***is not critical***." '402 Patent at 18:26–30. The specification also states that biocompatible component 12 and therapeutically active component 14 "can be positioned in different areas of the strand 10." '402 Patent at 17:47–50. The specification also describes six examples of "how marker 30 can be associated with the strand," as shown in Figures 3A–F.[14] *See* '402 Patent at 18:33–52. Figure 3A discloses an embodiment in which the "marker" is "in the form of a ribbon, filament, strip, thread, or wire . . . ***placed in the center and along the length of cylindrical strand***," and in Figure 3C (below), the "marker" is present as "a coil made of a radiopaque substance ***running through the length of cylindrical strand***." *Id.* at 18:35–43.

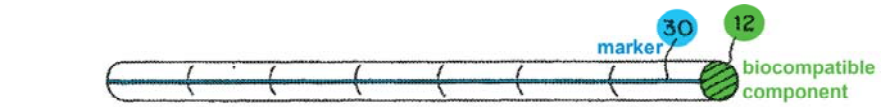

FIG. 3C

The embodiment in Figure 3C has a "hollow interior" that is not necessarily "defined by ***and inside***" of the "marker" (30), as Merck's construction would require. Instead, the "marker" "run[s] through the length of the cylindrical strand" of the strand, bounding a "hollow interior" on its outer surface between the biocompatible component (12). *Id.* at 18:40–43. Similarly, in another embodiment, a "polymeric coating" surrounds the "marker" component running through the center of the strand. '402 Patent at 7:63–65.

The specification also states that, in another embodiment, "the radiopaque marker 30 is

[14] Although the specification describes the various placements of "marker 30," that marker is "not shown except in Fig. 3C." '402 Patent at 18:12–17, 18:35–52.

dispersed throughout the strand in a stippled pattern." '402 Patent at 18:50–52. Similarly, dependent claim 10 of the '401 Patent recites a strand "wherein the agent is mixed together with the marker component." Merck's "exemplary diagram" (Merck Op. Br. at 27) thus distorts the various ways this can be implemented in embodiments of the claimed invention.

Merck's construction requiring that the "hollow interior" be "***defined by and inside***" of the marker excludes various embodiments in the specification. Because Merck failed to point to any disclaimer warranting such a limiting construction, it should be rejected. *See Oatey*, 514 F.3d at 1276–77.

Second, Merck's construction seemingly requires the presence of an "***empty space***" at all times. Merck Op. Br. at 25–26. But that is again inconsistent with the claim language itself and teachings of the specification. Something can be "hollow" but not necessarily "empty." For example, as described in the claims, the "hollow interior" is not ***empty*** when the "therapeutic, prophylactic, and/or diagnostic agent . . . are ***disposed within*** the hollow interior" as taught and claimed in the patent. '835 Patent at Claims 1 and 20. Merck's construction, which focuses on the "marker component" while ignoring the surrounding claim language reciting other elements that may partially or completely fill that space, is wrong. *See, e.g.*, *Pause Technology, LLC v. TiVo, Inc.*, 419 F.3d 1326, 1331 (Fed. Cir. 2005) (rejecting construction that ignored claim language, since "[p]roper claim construction . . . demands interpretation of the entire claim in context, not a single element in isolation").

Merck's citation to the specification regarding the "cavity" of a brachytherapy strand in support of their construction that "hollow denotes empty space" (Merck Op. Br. at 25) ignores that the following sentence states that the cavity is designed to "accept and envelope" another component and thus does not remain "empty." *See* '402 Patent at 15:24–29.

Finally, Microspherix's construction does not "nullif[y]" the word "hollow," because claim terms are not to be read in isolation. Merck Op. Br. at 24; *Pause Tech.,* 419 F.3d at 1331. Microspherix's construction appropriately equates "hollow" with "space," and while the claimed "hollow interior" could remain "hollow," other claim language indicates that it may be occupied by the therapeutic agent or biocompatible component. '401 Patent at Claim 9 ("The flexible strand according to claim 1, wherein the hollow interior comprises a biocompatible component."). Consideration of the claim language as a whole does not render "hollow" meaningless.

The Court should reject Merck's constructions that improperly attempt to redraft the claims by adding in two limitations in conflict with the intrinsic record and disclosed embodiments.

H. "flexible"

"Flexible" has a plain and ordinary meaning that does not require construction.[15] Merck nonetheless argues construction is necessary, and proposes a construction that is yet again inconsistent with the intrinsic record and unnecessarily limiting. The most that Merck can say in support of its construction is that "[t]he specification is not inconsistent." Merck Op. Br. at 32. This is far from the robust support Microspherix's proposed construction finds in the specification. Indeed, the specification explicitly prescribes the meaning and boundary of "flexible"—not "rigid or flaccid." '402 Patent at 22:32–35. Merck's own expert agrees with Microspherix's construction, having testified that "[e]verybody understands what flexible is," which is "not rigid." Park Tr. 96:14–97:24. The specification also demonstrates why Merck's proposed construction is incorrect—"flexible" is more than just "capable of bending" and includes flexibility "in ***any*** direction," including being turned, bowed, or twisted. '402 Patent at 22:40–41.

[15] The PTAB upheld the validity of the Asserted Claims without the need to construe "flexible." *See* D.I. 104, Ex. 30 ('401 IPR, Paper 44) at 6.

Moreover, far from being indefinite,[16] the specification also provides specific examples of what is and is not "flexible." '402 Patent at 2:66–3:8 ("[S]trands of permanent seeds like those described in U.S. Pat. No. 4,754,745 to Horowitz or U.S. Pat. No. 5,322,499 to Liprie are still too ***inflexible*** . . . . Similarly, the wire coils described in U.S. Pat. No. 6,436,026 to Sioshansi, although ***flexible***."). Indeed, because the specification provides examples that allow a POSA to compare a potentially infringing product, such a term of degree is not indefinite. *See Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017) (explaining that a term is not indefinite if intrinsic evidence "allow[s] a [POSA] to compare a potentially infringing product 'with the examples in the specification") (citation omitted); *see also Guangdong Alison Hi-Tech Co. v. Int'l Trade Comm'n*, 936 F.3d 1353, 1363 (Fed. Cir. 2019) ("Under our case law, examples in the specification may be used to inform those skilled in the art of the scope of the invention with reasonable certainty—thus demonstrating that the term is not indefinite.").

In arguing against Microspherix's construction, Merck vaguely asserts that "the specification reveals that flaccid and rigid are not exclusive of flexible," quoting two passages in the specification. Merck Op. Br. at 33 (quoting '402 Patent at 22:23–25 ("Where the ***spacer*** is made of a relatively ***flexible*** material, the ***chain*** can be relatively ***flaccid***.") and 22:32–35 ("Where the chain is endowed with the flexibility of an elastic polymer or similar substance, the chain may be considered to be variably flexible ***rather than*** rigid or flaccid.")). However, neither passage supports its argument. To the extent Merck relies on the first passage (22:23–25) to suggest that something cannot be both flexible and flaccid, the statement refers to two distinct elements (a spacer and a chain), one of which is flexible, the other flaccid. Merck's reliance on the second

[16] To the extent the Court chooses to decide indefiniteness at a later point in time—as is the common approach in this District—Microspherix reserves the right to further address the issue at that time.

passage (22:32–35) fares no better, as it expressly distinguishes "flexible" from "rigid or flaccid," which is consistent with Microspherix's proposed construction.

Without any intrinsic support, Merck relies on Microspherix's prior statements and expert testimony from the IPR proceedings "proposing 'flexible' as 'capable of being flexed: capable of being turned, bowed, or twisted without breaking.'" Merck Op. Br. at 32. Such arguments and testimony instead confirm that Merck's construction is improperly limited only to "bending," and that the plain and ordinary meaning is broader than that (*i.e.*, including capable of being turned, bowed, or twisted).

I. "rod"

Claim 1 of the '402 patent recites a "strand." The parties agree that a "strand" means an "elongated implant." D.I. 94-1 (JCCS) at 2. Despite Merck's contentions, there are no genuses and species of "strands" presented in the '402 Patent. Merck Op. Br. at 31 ("claimed configurations of strand (of which 'rod' is a sub-species)"). Rather, the specification provides ***examples*** of strands (e.g., rods, cylinders, chains of seeds, rings, and coils) without reference to any hierarchy. *See generally* '402 Patent at cols. 15–18; 22:51–59.

Claim 5 of the '402 Patent narrows claim 1 to strands "*in the form* of a rod or cylinder." Just as Merck contends "a chain of cylindrical seeds could generally be cylinder shaped," a chain of rod seeds could generally be rod shaped and thus fall within the scope of claim 5, which requires the strands to be "*in the form of* a rod." Merck Op. Br. at 31. Claim 5 does not limit the shape of the strand to "a unitary rod," as Merck contends, thus excluding other embodiments of strands, including chains of rod-shaped seeds.

Merck fails to point to any evidence that the claimed "rod" should be limited to a "***unitary***" cylinder. That is because the word "unitary" does not appear anywhere in the patents or the intrinsic evidence. Nor does it appear in the extrinsic evidence Merck cites. D.I. 104, Ex. 17 ("Rod,"

Dorland's) ("l. a straight, slim mass of substance"); Ex. 18 ("Rod," Stedman's) ("1. A slender cylindric structure or device"). Merck even fails to cite to the one part of the specification that discusses "rod" in support of its construction—because it does not in fact support its construction. '402 Patent at 22:51–59. Instead, Merck relies on Figures 1 and 2 to argue "a rod is a single, unitary structure." Merck Op. Br. at 31. However, these Figures relate to ***strands***, not rods. '402 Patent at 15:21–23 ("FIG. 1 is a schematic side view of a cylindrically shaped brachytherapy ***strand***. FIG. 2 is a schematic side view of a hollow tube-shaped brachytherapy ***strand***."). There is simply no support for Merck's "unitary" construction.

The Federal Circuit has held that, "[u]nless the claims, the specification, or the prosecution history require that the particular component be a single, one-piece structure, a court normally will not read that limitation into the claim." *Textron Innovations Inc. v. Am. Eurocopter Corp.*, 498 F. App'x 23, 30 (Fed. Cir. 2012). Merck's construction limiting rod to "unitary" is unsupported by the record, and contravenes Federal Circuit precedent, warranting rejection.[17]

IV. CONCLUSION

For the reasons discussed above, Microspherix respectfully requests that the Court adopt its proposed constructions of the disputed terms.

[17] Merck's reliance on *Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296, 1309 (Fed. Cir. 2017) is misplaced, as there, the Court did not read an ***additional*** limitation into the claims, and instead it relied on an example to provide an "objective standard by which to measure the scope" of an ***existing*** limitation ("efficient mixing").

Dated: January 14, 2021

/s/ *David N. Draper*

David N. Draper
Christopher DeCoro
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446–4800
david.draper@kirkland.com
christopher.decoro@kirkland.com

Of Counsel:

James F. Hurst, P.C. (admitted *pro hac vice*)
Marcus E. Sernel, P.C. (admitted *pro hac vice*)
Tasha Francis Gerasimow (admitted *pro hac vice*)
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
Tel: (312) 862–5230
james.hurst@kirkland.com
msernel@kirkland.com
tasha.gerasimow@kirkland.com

Stefan Michael Miller (admitted *pro hac vice*)
Ashley Ross (admitted *pro hac vice*)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
Tel: (212) 446–6479
stefan.miller@kirkland.com
ashley.ross@kirkland.com

Attorneys for Plaintiff Microspherix LLC